

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MICHAEL J GAST

Appeal No. 2001-1819¹
Application No. 08/886,072

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-17 and 23-29, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method of contraception which comprises administering to a female of child bearing age a combination of a progestin at a daily dosage selected from the group consisting of 40-500 µg trimegestone, and 250 µg – 4 mg dienogest, and an estrogen at a daily dosage equivalent in estrogenic activity to 1-20 µg ethinyl estradiol for 23-25 days beginning on day 1 of the menstrual cycle, and

¹ We find this appeal is related to Appeal No. 2001-1023 (Application No. 08/887,163), accordingly we have considered them together.

wherein the same dosage of the progestin and estrogen combination is administered in each of the 23-25 days.

The references relied upon by the examiner are:

Bennink	5,418,228	May 23, 1995
Barcomb	5,547,948	Aug. 20, 1996
Spona et al. (Spona)	5,583,129	Dec. 10, 1996
Oettel et al. (Oettel)	5,633,242	May. 27, 1997
Upton (European Patent Application)	0,253,607	Jan. 20, 1988

GROUND OF REJECTION

Claims 1-17 and 23-29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bennink, Spona² and Upton in view of Oettel and Barcomb.

We reverse.

DISCUSSION

As set forth in In re Dow Chemical Co. 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988), “[t]he consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art.”

On this record, the examiner finds (Answer, page 3) that Bennink, Spona and Upton teach contraceptive methods, compositions and kits “employing

² We note that Spona, et al., United States Patent No. 5,583,129, relied upon by the examiner in the Answer, is not the same reference relied upon in the Final Rejection, which was Spona, et al., WO 95/17194 (June 29, 1995). The examiner provides no explanation for changing references. We note, however, that the change in references appears to result in a new ground of rejection. To the extent the examiner has “switched horses” in the Answer and presents a different ground of rejection than that developed during prosecution, we note, as set forth in 37 C.F.R. § 1.193(a)(2) (1998), “[a]n examiner’s answer must not include a new ground of rejection....” We emphasize that the Answer was mailed after the effective date of this rule, and therefore the examiner erred in introducing a new ground of rejection in the Answer. Nevertheless, given our disposition, we find this error harmless.

progestogenic and estrogenic compounds to be administered in particular amounts on a specified dosage schedule, are known in the art.” The examiner recognizes (id.) “[t]he claims differ in that they are drawn to methods and kits employing particular progestogenic and estrogenic compounds in particular amounts on a specified dosage schedule.”

To make up for this deficiency in Bennink, Spona and Upton, the examiner affirmatively states (Answer, page 4) “[a]ny compound with progestogenic activity would be reasonably expected to be useful in combined oral contraceptive methods, absent evidence to the contrary.” In support of these conclusions the examiner cites Oettel and Barcomb (id.) which according to the examiner “show that progestogenic activity of compounds claimed herein is known in the art.

In reviewing the prior art relied on by the examiner, appellant finds (Brief, pages 4-6) that none of the prior art teaches dienogest and the only reference that teaches trimegestone is Barcomb. However, appellant finds (Brief, page 6) that while Barcomb identifies trimegestone as a hormonal steroid “suitable for incorporation into the sugar coated formulation [disclosed in Barcomb for the controlled release of steroid formulations], ... Barcomb does not teach or even suggest the use of the steroid formulation containing trimegestone as a contraceptive for 23-25 days per menstrual cycle.” According to appellant (id.) “Barcomb does not even teach the use of trimegestone as a contraceptive at all.”

The examiner recognizes (Answer, page 4) appellant’s arguments “that each of the references provides a piece of applicant’s invention, that there is no motivation to combine the references and that hindsight analysis is utilized in the

rejection.” Nevertheless, the examiner does not find appellant’s arguments persuasive “since the references clearly teach the use of a progestogen/ estrogen combination....”

The examiner, however, appears to miss the point of appellant’s arguments. Appellant’s claimed method requires, inter alia, administering to a female a combination of the progestin, trimegestone or dienogest, together with an estrogen for 23-25 days, wherein the same dosage of the progestin and estrogen combination is administered in each of the 23-25 days. The examiner recognizes that the claims differ from Bennink, Spona and Upton in that they require “particular progestogenic and estrogenic compounds in particular amounts on a specified dosage schedule.” See Answer, page 3. Of the two references relied on to make up for the deficiency in Bennink, Spona and Upton, only Barcomb teaches the claimed progestin – trimegestone. However, as explained by appellant (Brief, page 6) “Barcomb does not even teach the use of trimegestone as a contraceptive at all.”

Prima facie obviousness based on a combination of references requires that the prior art provide “a reason, suggestion, or motivation to lead an inventor to combine those references.” Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). On this record, the only suggestion to combine the references is found in appellant’s specification and the examiner’s unsupported conclusion that “[a]ny compound with progestogenic activity would be reasonably expected to be useful in combined oral contraceptive methods....”

The examiner, however, fails to provide any evidence to suggest that trimegestone or dienogest are equivalent to the progestins disclosed in the primary references, wherein one would reasonably expect them to be useful in appellant's claimed method. To establish a prima facie case of obviousness, there must be both (1) a suggestion or motivation to modify the references or combine reference teachings and (2) a reasonable expectation of success. See Dow; In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

On this record we find neither a suggestion to combine the prior art, nor a reasonable expectation of success. Accordingly, we reverse the rejection of claims 1-17 and 23-29 under 35 U.S.C. § 103 as being unpatentable over Bennink, Spona and Upton in view of Oettel and Barcomb.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

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American Home Products Corporation
Patent Section
Five Giralda Farms
Madison NJ 07940-0874